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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,637	11/14/2003	Robert J. Dunki-Jacobs	END-5240	2410

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
3737	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/713,637	DUNKI-JACOBS ET AL.	
	Examiner	Art Unit	
	Amanda L. Lauritzen	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 5-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 5-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Response to Arguments

Applicant's arguments filed 6 July 2007 have been fully considered and are not persuasive and/or are moot in view of the new grounds of rejection.

Regarding teachings within Kovacs '683 for marking target cells, col. 1, line 65 details marking tissues with a dye. Various other passages are related to administering a substance to the patient and determining the presence or levels of specific chemicals within the body (col. 3,lines 10-33; also col. 4, lines 48-49). The encapsulated detector is naturally directed through a body lumen as it passes through the GI tract and/or implantation results in directed positioning of the device. The method is understood to include mathematically analyzing signals for determining the presence or levels of specific chemicals and/or sensing physical parameter values related to the organs and tissues.

DETAILED ACTION

Priority

1. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 12-27 are rejected under 35 U.S.C. 102(b) or alternatively under 35 U.S.C. 103(a) as being unpatentable over Kovacs et al. (US 5,833,603).

Kovacs et al. disclose a system and method for detecting tissues comprising an encapsulated detector and administering a substance for associating with (or marking) a target tissue, the substance being capable of being detected by the detector for determining the presence or levels of specific chemicals within a patient and "sensing physical parameter values directly related to the patient's organs and tissues" (col. 1, line 65; also col. 3, lines 10-33; col. 4, lines 45-49). The signals detected are mathematically analyzed to determine whether a particular tissue is present in the patient, examples being temporary implants, prostheses, patient organs, and tissues (col. 3, lines 24-32).

Regarding claims 13-18, Kovacs et al. further disclose method steps of verifying at least one component and concentration (amount of chemical or biochemical substance) of the physical properties of the tissue, cell, and biochemical components of a region of interest. While Kovacs et al. do not explicitly state that the detection substance is a monoclonal body, peptide, nanoparticle, mRNA and DNA corresponding to a generic monoclonal antibody, and liposome, these are inherent inherent properties of biochemical composition of the tissues and cells (col.6, lines 26-36).

Regarding claims 19-23, Kovacs et al. disclose that the biosensor detects energy spectra via an optical or photosensor, which is used along with dye to acquire optical radiation. Although Kovacs et al. do not explicitly state use of radioisotopes, the dye solution with radiation optical acquisition is inherent that the dye solution must be a radioactive substance or a radioisotope (col. 1, lines 56-65; col. 4, lines 34-44; col. 5, lines 5-26).

Regarding claims 24-27, Kovacs et al. further disclose methods in which the sensor is a spectrophotometer acquiring multiple images of data from a region of interest with predetermined spectrum, wavelengths and position to detect optical spectrum, i.e., spectral response pattern (col. 1, line 66 – col. 2, line 11).

3. Claims 1, 5-11 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kovacs et al. '603 in view of Iddan et al. (US 5,604,531) and Okada et al. (US 5,424,546).

Kovacs et al. disclose a system for detecting tissues comprising a capsule comprising a detector, a substance for associating with a target tissue where the substance is capable of being detected by the detector and a machine for verifying at least one of the detector and substance are suitable for use (col. 3, line 10 – col. 4, line 59; col. 6, lines 8-56). In addition, Kovacs et al. disclose that the capsule includes multiple detectors, a radiation detector, magnetic detector, and single analyzer for each detector (col. 4, lines 35-44). Although Kovacs et al. disclose implantation of the sensor device, Kovacs et al do not disclose that the capsule is a swallowable or that the capsule material is coated to allow the capsule to pass through the gastro-intestinal (GI) tract. However, Iddan et al. teaches a similar capsule detector where the device is swallowable and coated with material to allow the detector to pass through the GI tract (col. 1, lines 34-40; col. 3, line 8 – col. 5, line 6). In addition, neither Kovacs et al. nor Iddan et al. specifically disclose that detector pulse shaping device is in direct communication with a single channel analyzer configured to analyze the voltage output; however, Okada et al. teach an endoscope or catheter with a detector includes single channel analyzer that counts the detected photons, i.e. voltage output from the pulse shaping device (col. 10, lines 13-29). Iddan et al., at col. 3, lines 32-33, teach a detector disposed within a capsule. Okada et al. disclose two

radiation detectors, pulse-shaping circuits and a single-channel analyzer at col. 10, lines 13-29, and establish that this technology is known within the art of performing photon counting operations for an organism injected (i.e., marked) with a radioactive substance (col. 1, lines 19-22). The components of Okada et al. could be encapsulated and coated for ease of transfer through the GI tract (as taught by Iddan et al. at col. 1, lines 34-40; col. 3, line 8 – col. 5, line 6). It would have been obvious to modify the device of Kovacs et al. to be swallowable and coated as taught by Iddan et al. in order to enable natural progression through the GI tract, and to further modify to include the pulse-shaping circuits and single channel analyzer of the probe of Okada et al. for the purpose of measuring the concentration of radiation in a certain area of an object or organism treated with a radioactive substance (col. 1, lines 19-22; 26-27).

Both Okada et al. and Kovacs et al. disclose multiple detectors and/or an arrangement with two radiation detectors, but neither is specific to the detectors being disposed at opposite ends of the capsule; however, this feature presents no novel or unexpected result over the detector layout disclosed in the references. Disposing detectors oppositely in lieu of the arrangements disclosed in either Okada or Kovacs et al. solves no stated problem and is therefore considered an obvious matter of design choice within the skill of the art.

Regarding claim 28, the substance associated with the particular tissue that is detected can be taken either as the dye marking substance as in Kovacs et al. or the radioactive marking substance as in Okada et al. The "target tissue" or "particular tissue" as recited in the claims are interpreted to encompass any desired tissue of interest. Okada et al. cites "detecting the distribution of radiation" in an organism (col. 2, lines 7-8). Different tissue types will naturally have varying affinity for radioactive substances and likewise, the distribution of radiation will

depend on that affinity. Therefore a measure of the distribution of radiation will correspond to target tissue distribution and the presence of target tissues with a high affinity for radiation will be identifiable.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda L. Lauritzen whose telephone number is (571) 272-4303. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALL
9/17/2007

ELENI MANTIS MERCADER
SUPERVISORY PATENT EXAMINER